EUROPEAN COMMISSION

Brussels, 25.10.2010
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COMMISSION DECISION

of 25.10.2010

amending the marketing authorisation for "Faslodex - Fulvestrant", a medicinal product for human use, granted by Decision C(2004)851

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

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(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application submitted by AstraZeneca UK Limited on 22 November 2009 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to Commission Regulation (EC) No 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products[3], and in particular Article 17(2) thereof,

Having regard to the notification submitted by AstraZeneca UK Limited, under Article 15(1) of Regulation (EC) No 1234/2008,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 23 September 2010,

Whereas:

(1) An examination of the major variation(s) type II to the terms of the marketing authorisation for the medicinal product "Faslodex - Fulvestrant", which is entered in the Community Register of Medicinal Products under number(s) EU/1/03/269/001-002 and the placing on the market of which was authorised by Decision C(2004)851 of 10 March 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 159, 27.6.2003, p. 24.
[3] OJ L 334, 12.12.2008, p. 7.

European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[4].

(2) It is therefore appropriate to accept the application(s) in respect of (a) major variation(s) to the terms of the marketing authorisation and to amend Decision C(2004)851 accordingly.

(3) The European Medicines Agency has informed the marketing authorisation holder and the Commission of its favourable opinion on a minor variation notified between 15 March 2010 and 23 September 2010.

(4) The marketing authorisation should be updated and Decision C(2004)851 of 10 March 2004 should therefore be amended accordingly. The Community Register of Medicinal Products should also be updated.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)851 is amended as follows:

1) The following notification for a minor variation is added to the marketing authorisation:

Application number	Scope (EU numbers affected)
EMEA/H/C/540/IB/22	B.II.e.5.a).2 (EU/1/03/269/002)

2) The following number is added to Article 1 and entered in the Community Register of Medicinal Products:

EU/1/03/269/002	Faslodex - 250 mg/5 ml - Solution for injection - Intramuscular use - pre-filled syringe (glass) - 5 ml - 2 pre-filled syringes + 2 safety needles

3) Annex I is replaced by the text set out in Annex I to this Decision;

4) Annex II is replaced by the text set out in Annex II to this Decision;

5) Annex III is replaced by the text set out in Annex III to this Decision.

[4] OJ L 311, 28.11.2001, p. 67.

Article 2

This Decision is addressed to AstraZeneca UK Limited, Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom.

Done at Brussels, on 25.10.2010.

For the Commission
Paola TESTORI COGGI
Director-General